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Appendix 7 – 510(k) Summary for Modified Alma Lasers Family of Accent™ Radiofrequency (RF) Systems [Accent, Accent XL, Accent Elite]

JAN 2 1 2011

I. General Information

Sponsor/ 510(k) Owner Address and Establishment Registration #	**Sponsor** Alma Lasers, Inc. 485 Half Day Rd. Suite No. 100 Buffalo Grove, IL 68900, USA FDA Registration #: 3004167969		
	Tatiana Epstein VP RA Alma Lasers, Inc.	Telephone: Facsimile: Email:	(224) 377-2011 (224) 377-2050 tatianae@almalasers.com
Contact Person:	Main Contact: Tatiana Epstein VP RA Alma Lasers, Inc.	Telephone: Facsimile: Email:	(224) 377-2011 (224) 377-2050 tatianae@almalasers.com
	Secondary Contact: Avi Farbstein EVP and GM North America Alma Lasers, Inc.	Telephone: Facsimile: Email:	(224) 377-2011 (224) 377-2050 Avi.Farbstein@almalasers.com

Summary Preparation Date: January 20, 2011

II. Names

Device Names:	Modified Alma Lasers Family of Accent™ Radiofrequency (RF) Systems [Accent, Accent XL, Accent Elite]
Primary Classification Names:	Electrosurgical Cutting and Coagulation Device & Accessories; Massager, vacuum, light induced heating; Electric therapeutic massager

III. Predicate Devices

- Accent™ (K070004), cleared 04/23/2007,
- Alma Lasers Family of Accent™ Radiofrequency (RF) Systems [Accent, Accent XL] (K072699), cleared 09/19/2007 and
- Accent Uniform Massager Handpiece/Module (K082622), cleared 01/12/2009.

IV. Product Description

The Alma Lasers Accent Elite system similar to Accent™ RF Systems [Accent, Accent XL] is comprised of the following main components:

- Console

  - Bipolar RF module
  - Unipolar RF module (UniLarge)
  - UniForm (RF and Massage) module
- Control panel
- Footswitch.

Modules are used to deliver radiofrequency energy to the treatment site. Each RF module consists of the following components:

- Handle – used for holding the module
- Trigger – activates the radiofrequency energy emission when pressed in Ready mode
- Applicator tip – establishes contact with the patient's skin
- Thermoelectric cooler – integrated within the module, provides internal module cooling
- RF emission indicator – blue LED illuminates prior to- and during RF emission
- Umbilical cable – contains coolant tubes, RF-power cable and the communication cable that controls the operation of the module
- Module connector – connects the module to its port. It incorporates an integrated impedance matching network (IMN) and a memory chip which stores information about the module and the parameter settings.

The UniForm module additionally employs a massaging mechanism that works in conjunction with the RF energy application.

The Accent Elite is a computerized system with embedded software that controls its operation. The software also runs the graphical user interface, which enables user-friendly control of the system operation.

V. Intended Use and Indications for Use

Intended Use

The Modified Alma Lasers Family of Accent™ Radiofrequency (RF) Systems [Accent, Accent XL, Accent Elite] is intended for use in dermatologic and general surgical procedures.

Indications for Use

The Alma Lasers Family of Accent™ RF Systems [Accent, Accent XL, Accent Elite] is indicated for the non-invasive treatment of wrinkles and rhytids using a combined treatment with unipolar and bipolar handpieces.

The massager component of the Alma Lasers Accent UniForm Handpiece is intended for use with the Modified Alma Lasers Family of Accent™ RF Systems [Accent, Accent XL, Accent Elite] to provide:

- Temporary reduction in the appearance of cellulite.

Simultaneous application of the RF energy and mechanical manipulation of the skin is intended for use with the Modified Alma Lasers Family of Accent™ RF Systems [Accent, Accent XL, Accent Elite] to provide:

- Temporary reduction in the appearance of cellulite.

VI. Rationale for Substantial Equivalence

The Modified Alma Lasers Family of Accent™ Radiofrequency (RF) Systems [Accent, Accent XL, Accent Elite] shares the same indications for use, operation principle, technical and functional capabilities, and therefore is substantially equivalent to the predicate Accent™ Family of RF Systems. Determination of substantial equivalence is based on an assessment of non-clinical performance data.

Comparison with the Predicate Devices

Characteristic	**K101147** Modified Alma Lasers Family of Accent™ RF Systems [Accent, Accent XL, Accent Elite]	**K072699** Alma Lasers Family of Accent™ RF Systems [Accent, Accent XL]	**K070004** Accent ™ Alma Lasers
Product Code & Regulation No.	GEI – Electrosurgical, Cutting and Coagulation Device & Accessories; 878.4400	GEI – Electrosurgical, Cutting and Coagulation Device & Accessories; 878.4400	GEI – Electrosurgical, Cutting and Coagulation Device & Accessories; 878.4400
	Massager, vacuum, light induced heating NUV; 878.4810	Massager, vacuum, light induced heating NUV; 878.4810	
	Massager, therapeutic, electric ISA; 890.5660	Massager, therapeutic, electric ISA; 890.5660	
Intended Use	Intended for use in dermatologic and general surgical procedures	Intended for use in dermatologic and general surgical procedures	Intended for use in dermatologic and general surgical procedures
Indications for Use	Indicated for: • The non-invasive treatment of wrinkles and rhytids using a combined treatment with Unipolar and Bipolar handpieces	Indicated for: • The non-invasive treatment of wrinkles and rhytids using a combined treatment with Unipolar and Bipolar handpieces	Indicated for: • The non-invasive treatment of wrinkles and rhytids using a combined treatment with Unipolar and Bipolar handpieces
	• Temporary reduction in the appearance of cellulite by the use of the massage component or simultaneous application of the RF energy and mechanical manipulation of the skin	• Temporary reduction in the appearance of cellulite by the use of the massage component or simultaneous application of the RF energy and mechanical manipulation of the skin	
Treatment Energy	• Radio frequency (RF)	• Radio frequency (RF)	• Radio frequency (RF)
RF Frequency	40,680 MHz	40,680 MHz	40,680 MHz
RF Output Power & Delivery Devices			
		• UniPolar	• UniPolar
	• UniLarge	• UniLarge	
• UniPolar	• UniForm ▶ Massager + RF ▶ RF alone	• UniForm ▶ Massager + RF ▶ RF alone	
• BiPolar	• BiPolar	• BiPolar	• BiPolar

Characteristic	K101147 Modified Alma Lasers Family of Accent™ RF Systems [Accent, Accent XL, Accent Elite]	K072699 Alma Lasers Family of Accent™ RF Systems [Accent, Accent XL]	K070004 Accent ™ Alma Lasers
Energy Output Mode(s)	• UniPolar (i.e. Monopolar) – volumetric heating • BiPolar – superficial heating	• UniPolar (i.e. Monopolar) – volumetric heating • BiPolar – superficial heating	• UniPolar (i.e. Monopolar) – volumetric heating • BiPolar – superficial heating
Handpiece Dimensions (mm)	• UniLarge 159 x 158	• UniPolar 159 x 158 • UniLarge	• UniPolar 169 x 205 • BiPolar 167 x 203
	• BiPolar 153.3 x 158	• BiPolar 153.3 x 158	
	• UniForm 176 x 185	• UniForm 176 x 185	
Module Connection	• Umbilical cable • Detachable with a memory chip	• Umbilical cable • Detachable with a memory chip	• Umbilical cable • Permanently connected (hard-wired)
RF Electrode TEC Cooling	Yes	Yes	Yes
Electrical Reqs	110–120 V, 50–60 Hz, 5A	110–120 V, 50–60 Hz, 5A	110–120 V, 50–60 Hz, 5A
Console Size ["]	12 x 25 x 14	26 x 17 x 16	21 x 17 x 38
Weight [lb]	36.5	55	110

Performance Testing

The following safety performance testing was performed and submitted as part of the 510(k) premarket notification submission:

- IEC 60601-1-2: 2004: Medical electrical equipment - Part 1: General requirements for safety: Electromagnetic compatibility
- IEC 60601-1:1988, Amendment 1:1991, Amendment 2:1995 Medical electrical equipment – Part 1: General requirements for safety
- IEC 60601-2-2:2006 - Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories

The results of the performance testing of the Accent Elite system show compliance with applicable FDA Recognized Consensus Standards.

The review of the indications for use, technical characteristics and performance testing data provided demonstrates that the Accent Elite RF System is substantially equivalent to the predicate Accent™ RF systems, is safe and effective, and performs at least as safely and effectively as the predicate Alma Lasers Family of Accent™ Radiofrequency (RF) Systems [Accent, Accent XL] for the intended use and indications.

VII. Conclusion

The Alma Lasers Accent Elite RF System shares the same indications for use, similar design, performance and functional features as the predicate Accent™ RF Systems.
The Modified Alma Lasers Family of Accent™ Radiofrequency (RF) Systems [Accent, Accent XL, Accent Elite] is found to be substantially equivalent to the predicate Alma Lasers Family of Accent™ RF Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Alma Lasers, Inc.
% Ms. Tatiana Epstein
485 Half Day Rd., Suite #100
Buffalo Grove, Illinois 60089

JAN 21 2011

Re: K101147
Trade/Device Name: Modified Alma Lasers Family of Accent™ Radiofrequency (RF) Systems [Accent, Accent XL, Accent Elite]
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: NUV, GEI, ISA
Dated: January 10, 2011
Received: January 13, 2011

Dear Ms. Epstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28; 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): **K101147**

Device Name: **Modified Alma Lasers Family of Accent™ RF Systems [Accent, Accent XL, Accent Elite]**

Indications for Use:

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Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101147